

**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

MELISSA VOTER, Derivatively on Behalf of
CORMEDIX INC.,

Plaintiff,

vs.

KHOSO BALUCH, JANET DILLIONE,
ALAN W. DUNTON, MYRON KAPLAN,
STEVEN LEFKOWITZ, PAOLO F. COSTA,
GREG DUNCAN, MATTHEW DAVID, and
PHOEBE MOUNTS,

Defendants,

and,

CORMEDIX INC.,

Nominal Defendant.

Index No:

**VERIFIED SHAREHOLDER
DERIVATIVE COMPLAINT**

DEMAND FOR JURY TRIAL

Plaintiff Melissa Voter (“Plaintiff”), by and through her undersigned counsel, derivatively on behalf of Nominal Defendant CorMedix, Inc. (“CorMedix” or the “Company”), submit this Verified Shareholder Derivative Complaint (the “Complaint”). Plaintiff’s allegations are based upon her personal knowledge as to herself and her own acts, and upon information and belief, developed from the investigation and analysis by Plaintiff’s counsel, including a review of publicly available information, including filings by CorMedix with the U.S. Securities and Exchange Commission (“SEC”), press releases, news reports, analyst reports, investor conference transcripts, publicly available filings in lawsuits, and matters of public record.

NATURE OF THE ACTION

1. This is a shareholder derivative action brought in the right, and for the benefit, of CorMedix against its officers and directors (defined below) seeking to remedy Defendants' breach of fiduciary duties.

2. CorMedix is a biopharmaceutical company that focuses on developing and commercializing therapeutic products for the prevention and treatment of infectious and inflammatory diseases in the U.S. and internationally. The Company is focused on developing its lead product candidate DefenCath -- a purported novel antibacterial and antifungal solution -- designed to prevent costly and dangerous catheter-related bloodstream infections ("CRBSIs").

3. In July 2020, CorMedix completed submission of a New Drug Application ("NDA") to the U.S. Food and Drug Administration ("FDA") for DefenCath as a catheter lock solution with an initial indication for use of preventing CRBSIs in patients with end-stage renal disease who are receiving hemodialysis via a central venous catheter.

4. Defendants caused the Company to make materially false and misleading statements regarding the Company's business, operations, and compliance policies. Specifically, the Company made false and/or misleading statements and/or failed to disclose that: (i) deficiencies existed with respect to DefenCath's manufacturing process and/or at the facility responsible for manufacturing DefenCath; (ii) in light of the foregoing deficiencies, the FDA was unlikely to approve the DefenCath NDA for CRBSIs in its present form; (iii) the Company had downplayed the true scope of the deficiencies with DefenCath's manufacturing process and/or at the facility responsible for manufacturing DefenCath; and (iv) as a result, the Company's public statements were materially false and misleading at all relevant times.

5. On March 1, 2021, the Company issued a press release "announc[ing] that the

[FDA] cannot approve the [NDA] for DefenCath . . . in its present form.” The Company informed investors that the “FDA noted concerns at the third-party manufacturing facility after a review of records requested by FDA and provided by the manufacturing facility”; that the “FDA did not specify the issues and CorMedix intends to work with the manufacturing facility to develop a plan for resolution when FDA informs the facility of the specific concerns”; that, “[w]hen we are informed of the issues, we will schedule an investor conference call to provide an update on our expected timeline for resolution”; and that, “[a]dditionally, FDA is requiring a manual extraction study to demonstrate that the labeled volume can be consistently withdrawn from the vials despite an existing in-process control to demonstrate fill volume within specifications.”

6. On this news, the Company’s stock price dropped \$5.98 per share, or 39.87%, to close at \$9.02 per share on March 1, 2021.

7. On April 14, 2021, the Company announced that it would have to take additional steps to meet the FDA’s requirements for DefenCath’s manufacturing process, including “[a]ddressing FDA’s concerns regarding the qualification of the filling operation [that] may necessitate adjustments in the process and generation of additional data on operating parameters for manufacture of DefenCath.”

8. On this news, the Company’s stock price dropped \$1.44 per share, or 15.37%, to close at \$7.93 per share on April 14, 2021.

9. Finally, on May 13, 2021, the Company announced that “[b]ased on our analyses, we have concluded that additional process qualification will be needed with subsequent validation to address the deficiencies identified by FDA.” After an analyst pressed for clearer information on DefenCath’s manufacturing deficiencies on a conference call held that same day, Defendant Mounts, the Company’s Executive Vice President and General Counsel, disclosed, *inter alia*, that

“there are times when there may be unexpected results obtained”; that the FDA “expect[s] us to generate sufficient data to demonstrate that [the filling] process is a controlled process and is consistent with the agency’s requirements for good manufacturing practice”; that “sterility is a very important part of that process,” as well as “the accuracy in making sure the right volume of DEFENCATH is loaded into the vials”; that “we are talking about thousands of vials during the manufacturing run”; that the Company must “generat[e] of a lot of data to make sure that . . . all the equipment has been qualified for the intended use and every step in the manufacturing process has been qualified”; that “th[e] process needs to be very robust, [and] needs to be reproducible”; and that “the burden is on the manufacturer to demonstrate that the facility can do that process reducibly and generate the required product for commercial distribution.”

10. On this news, the Company’s stock price fell \$1.51 per share, or 19.97%, to close at \$6.05 per share on May 14, 2021.

JURISDICTION AND VENUE

11. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1331 in that this Complaint states a federal question: violations of Sections 10(b) and 21D of the Exchange Act. This Court has supplemental jurisdiction over the state law claims asserted herein pursuant to 28 U.S.C. § 1367(a). This action is not a collusive one to confer jurisdiction on a court of the United States which it would not otherwise have.

12. Venue is proper in this District pursuant to 28 U.S.C. §§ 1391 and 1401 because a substantial portion of the transactions and wrongs complained of herein occurred in this District, and Defendants have received substantial compensation in this District by engaging in numerous activities that had an effect in this District.

PARTIES

A. Plaintiff

13. Plaintiff Melissa Voter is an owner of CorMedix stock during the time when the Company was issuing false and misleading statements to the market. Plaintiff Voter continues to hold shares of CorMedix stock to the present.

B. Nominal Defendant

14. Nominal Defendant CorMedix is a Delaware corporation with principal executive offices located at 300 Connell Drive, Suite 4200, Berkeley Heights, New Jersey 07922.

C. Director Defendants

15. ***Defendant Khoso Baluch*** is the Chief Executive Officer (“CEO”) and a Director of the Company. The Company’s November 4, 2020 Proxy states that Defendant Baluch is not independent.

16. ***Defendant Janet Dillione*** (“Dillione”) is a Director of the Company. Defendant Dillione is a member of the Audit Committee.

17. ***Defendant Alan W. Dunton*** (“Dunton”) is a Director of the Company. Defendant Dunton is a member of the Audit Committee.

18. ***Defendant Myron Kaplan*** (“Kaplan”) is a Director of the Company and Chairman of the Board.

19. ***Defendant Steven Lefkowitz*** (“Lefkowitz”) is a Director of the Company. Defendant Lefkowitz is the Chairman of the Audit Committee.

20. ***Defendant Paolo F. Costa*** (“Costa”) is a Director of the Company.

21. ***Defendant Greg Duncan*** (“Duncan”) is a Director of the Company.

22. Defendants Baluch, Dillione, Dunton, Kaplan, Lefkowitz, Costa and Duncan are herein referred to collectively as the “Director Defendants”.

Officer Defendant

23. ***Defendant Matthew David*** (“David”) has served as the Company’s Chief Financial Officer (“CFO”) during the relevant paeriod.

24. ***Defendant Phoebe Mounts*** (“Mounts”) has served as the Company’s Executive Vice President and General Counsel during the relevant period.

25. The Director Defendants and Defendants David and Mounts are collectively referred to as the “Defendants”.

THE AUDIT COMMITTEE

26. The Audit Committee monitors the Company’s corporate financial statements and reporting and its external audits, including, among other things, the Company’s internal controls and audit functions, the results and scope of the annual audit and other services provided by the Company’s independent registered public accounting firm and the Company’s compliance with legal matters that have a significant impact on the Company’s financial statements.

27. The Audit Committee also consults with management and the independent registered public accounting firm prior to the presentation of financial statements to stockholders and, as appropriate, initiates inquiries into aspects of the Company’s financial affairs.

28. The Audit Committee is responsible for establishing procedures for the receipt, retention and treatment of complaints regarding accounting, internal accounting controls or auditing matters, and for the confidential, anonymous submission by the Company’s employees of concerns regarding questionable accounting or auditing matters.

29. In addition, the Audit Committee is directly responsible for the appointment, retention, compensation and oversight of the work of the independent registered public accounting firm, including approving services and fee arrangements. All related party transactions will be

approved by the Audit Committee before the Company enters into them.

BACKGROUND

30. The Company is a biopharmaceutical company that focuses on developing and commercializing therapeutic products for the prevention and treatment of infectious and inflammatory diseases in the U.S. and internationally. The Company is focused on developing its lead product candidate, DefenCath, a purported novel antibacterial and antifungal solution designed to prevent costly and dangerous CRBSIs.

31. In July 2020, CorMedix completed submission of an NDA to the FDA for DefenCath as a catheter lock solution with an initial indication for use of preventing CRBSIs in patients with end-stage renal disease who are receiving hemodialysis via a central venous catheter.

FALSE AND MISLEADING STATEMENTS

32. On July 8, 2020, the Company issued a press release, announcing that it had completed submitting the DefenCath NDA with the FDA for CRBSIs in patients with end-stage renal disease who are receiving hemodialysis via a central venous catheter (the “July 2020 Press Release”). That press release stated that “all of the modules for the Defencath™ [NDA] have been submitted to the [FDA]”; that “there has been ongoing dialogue with FDA as it reviews the submitted modules”; and that “[t]he NDA contained data from the Company’s Phase 3 trial, LOCK-IT-100, in patients undergoing hemodialysis for end-stage renal disease, which showed a 71% reduction in CRBSIs relative to the heparin control arm . . . with a good safety profile.”

33. The July 2020 Press Release also quoted Defendant Baluch, who represented that the Company was “very pleased to have completed the submission of the NDA, despite the limitations imposed by the COVID-19 pandemic, which delayed some required laboratory testing and our submission[,]” and that “[s]ubmission of our first NDA is an important milestone for

CorMedix and is a significant accomplishment by the Company.”

34. On August 10, 2020, the Company issued a press release reporting its results for the second fiscal quarter of 2020 and providing a business update (the “2Q20 Press Release”). That press release represented that the Company had “[c]ompleted the rolling submission and review of the [NDA] for Defencath to the FDA for the prevention of . . . CRBSIs[] in patients undergoing hemodialysis via catheter[,]” and that the Company “[c]ontinued to expand [...] efforts to prepare for the commercial launch of Defencath.”

35. The 2Q20 Press Release also asserted that the Company had invested significant funds into Defencath’s research and development (“R&D”), thereby indicating to the market that Defencath’s manufacturing was well-supported. Specifically, the 2Q20 Press Release stated that the Company recognized a “higher net loss . . . in 2020 compared with 2019 . . . due to increased expenses related to our preparations for Defencath’s commercial launch[,]” that “[w]e recorded significant increases in . . . R&D[,]” and that “R&D expense increased approximately 91% to \$5.7 million from \$3.0 million, mainly due to a \$3.4 million purchase of raw material that will be used in the production of Defencath for sale in the U.S. upon receipt of FDA marketing approval[.]”

36. Additionally, the 2Q20 Press Release quoted Defendant Baluch, who stated that “[w]e have made significant progress on our goal of bringing Defencath to the U.S. market as a catheter lock solution for hemodialysis”; that “[w]e also are making necessary preparations for the launch of Defencath in the U.S. hemodialysis market, following FDA approval”; and that “[w]e believe we have the team, the focus, and a therapy that will meaningfully improve patient outcomes and are excited about the opportunities in front of us.”

37. That same day, the Company filed a quarterly report on Form 10-Q with the SEC, reporting the Company’s financial and operating results for the quarter ended June 30, 2020 (the

“2Q20 10-Q”). The 2Q20 10-Q discussed the Company’s DefenCath NDA submission with the FDA, stating that “[i]n March 2020, the Company began the modular submission process for the NDA for Defencath for the prevention of CRBSI in hemodialysis patients, and recently announced on July 8, 2020, that submission of all modules for the NDA was completed”; that “[t]he Company requested Priority Review of the NDA, which if granted, would provide for a goal for the FDA of a six-month review period, instead of ten months for applications under standard review”; and that “[t]he Company has not been informed of any delays by the FDA in the review of the NDA[.]”

38. Appended as exhibits to the 2Q20 10-Q were signed certifications pursuant to the Sarbanes-Oxley Act of 2002 (“SOX”), wherein Defendants Baluch and David certified that “[t]he [2Q20 10-Q] fully complies with the requirements of Section 13(a) or 15(d) of the [Exchange Act], as amended[.]” and that “[t]he information contained in the [2Q20 10-Q] fairly presents, in all material respects, the financial condition and results of operations of the Company.”

39. On August 31, 2020, the Company issued a press release announcing the FDA’s acceptance for filing and priority review of the DefenCath NDA for CRBSIs (the “August 2020 Press Release”). That press release stated that the FDA “noted that it is planning to hold an advisory committee meeting to discuss the [NDA] application and that it had not identified any potential review issues at this time.”

40. The August 2020 Press Release also quoted Defendant Baluch, who represented that “[t]he NDA acceptance is truly a momentous achievement for CorMedix, the internal and external teams involved with the submission, and most importantly, the hemodialysis patient community[.]” and that the Company “[is] proud of [its] team for exceptional effort to get [the Company] to this point and look forward to bringing Defencath to patients to prevent the serious complications and costs associated with CRBSI in this significant patient population.”

41. In addition, the August 2020 Press Release quoted Defendant Mounts, who asserted that “the FDA’s acceptance of [the Company’s] first NDA as an essential step toward [the Company’s] goal of offering Defencath in the U.S. as the first antimicrobial catheter lock solution for the prevention of life-threatening CRBSI in hemodialysis patients[,]” that “[w]e are very appreciative that the [FDA] granted priority review and despite the ongoing pandemic,” and that “we look forward to continuing to work together [with the FDA] expeditiously to complete the review of the Defencath NDA to address an unmet medical need.”

42. On November 5, 2020, the Company issued a press release reporting its results for the third fiscal quarter of 2020 and providing a business update (the “3Q20 Press Release”). That press release represented that “CorMedix continues its interactions with the FDA regarding the . . . NDA[] for Defencath™ for the prevention of . . . CRBSIs[] in patients undergoing hemodialysis via central venous catheter[,]” and that “CorMedix has continued to expand its efforts to prepare for the commercial launch of Defencath[,]” including interactions with certain market participants, that “have been positive and clearly position CorMedix to ensure that, once Defencath is approved by the FDA, it will be in the best possible position to successfully launch in the US market.”

43. The 3Q20 Press Release also continued to assert that the Company had invested significant funds into Defencath’s R&D, thereby indicating to investors that Defencath’s manufacturing was well-supported. Specifically, the 3Q20 Press Release stated that “[o]perating expenses during the third quarter of 2020 . . . increase[d] . . . approximately 28%[,]” which “was due [in part] to a \$0.4 million, or 16%, increase in R&D expense”; that “[o]perating expenses during the nine-month period ended September 30, 2020 . . . increase[d] . . . 36%, due [in part] to a 32% increase in R&D expense”; and that “R&D expense for the first nine months of 2020 included approximately \$3.8 million in costs related to the purchase of raw materials and

manufacturing of Defencath prior to its potential marketing approval and also included increased staffing costs.”

44. In addition, the 3Q20 Press Release quoted Defendant Baluch, who stated that “[w]e have continued to make progress on our goal of bringing Defencath to the U.S. market as a catheter lock solution for hemodialysis”; that “[w]e look forward to discussing Defencath with the Antimicrobial Drugs Advisory Committee in January, ahead of the February 28, 2021 PDUFA date for the product”; that “[w]e also are making necessary preparations for the launch of Defencath in the U.S. hemodialysis market, following FDA approval”; and that “[w]e believe we have the team, the focus, the resources, and a novel catheter lock solution that will meaningfully improve patient outcomes and are excited about the opportunities in front of us.”

45. That same day, the Company filed a quarterly report on Form 10-Q with the SEC, reporting the Company’s financial and operating results for the quarter ended September 30, 2020 (the “3Q20 10-Q”). The 3Q20 10-Q contained substantively the same statements as referenced in ¶ 37, discussing the submission process for the DefenCath NDA while also advising that “[t]he FDA noted that it is planning to hold an advisory committee meeting to discuss the application and that it had not identified any potential review issues at this time[,]” and that “[t]he Company has not been informed of any delays by the FDA in the review of the NDA, but . . . pre-approval inspections are required for manufacturing sites.”

46. Appended as exhibits to the 3Q20 10-Q were substantively the same SOX certifications as referenced in ¶ 38, signed by Defendants Baluch and David.

47. On November 18, 2020, the Company issued a press release announcing the FDA’s decision that an advisory committee meeting for the DefenCath NDA for CRBSIs was not needed (the “November 2020 Press Release”). That press release advised that the FDA “noted that it was

planning to hold an advisory committee meeting to discuss the application for Defencath to be used as a catheter lock solution in hemodialysis patients for the prevention of [CRBSI] and that it had not identified any potential review issues at that time[.]” and that “CorMedix has been notified that based on the [FDA]’s ongoing dialogue with the Company, discussion at an advisory committee is not needed, and it will continue to work on the application with CorMedix during the remainder of the review cycle.”

48. The November 2020 Press Release also quoted Defendant Baluch, who asserted that the Company and the FDA were working closely together on the DefenCath NDA for CRBSIs, stating that “[w]e are very happy with the level of engagement between FDA and the CorMedix team during the NDA review process[.]” and that “[w]e look forward to completion of the review of the NDA and are considering all strategic options to be able to successfully bring Defencath to the U.S. market as soon as possible.”

49. In addition, the November 2020 press Release quoted Defendant Mounts, who likewise asserted that the Company and the FDA were working closely together on the DefenCath NDA for CRBSIs, stating that “[i]t is gratifying that the tremendous effort of the CorMedix team has resulted in continuing progress with the FDA in the review of the NDA and that the decision was made that no discussion with an advisory committee is needed[.]” and that “[w]e intend to continue our effort and dialogue with the [FDA] to ensure that the priority review process can be completed expeditiously to address the unmet medical need of hemodialysis patients for an antimicrobial catheter lock solution to prevent life-threatening CRBSI.”

50. The statements referenced in ¶¶ 32-49 were materially false and misleading because the Company made false and/or misleading statements, as well as failed to disclose material adverse facts about the Company’s business, operations, and compliance policies. Specifically,

the Company made false and/or misleading statements and/or failed to disclose that: (i) deficiencies existed with respect to DefenCath's manufacturing process and/or at the facility responsible for manufacturing DefenCath; (ii) in light of the foregoing deficiencies, the FDA was unlikely to approve the DefenCath NDA for CRBSIs in its present form; (iii) the Company had downplayed the true scope of the deficiencies regarding DefenCath's manufacturing process and/or at the facility responsible for manufacturing DefenCath; and (iv) as a result, the Company's public statements were materially false and misleading at all relevant times.

THE TRUTH BEGINS TO EMERGE

51. On March 1, 2021, the Company issued a press release "announc[ing] that the [FDA] cannot approve the [NDA] for DefenCath . . . in its present form." The Company informed investors that the FDA had noted concerns regarding DefenCath's manufacturing, stating:

[T]he [FDA] cannot approve the [NDA] for DefenCath . . . in its present form. FDA noted concerns at the third-party manufacturing facility after a review of records requested by FDA and provided by the manufacturing facility. FDA did not specify the issues and CorMedix intends to work with the manufacturing facility to develop a plan for resolution when FDA informs the facility of the specific concerns.

When we are informed of the issues, we will schedule an investor conference call to provide an update on our expected timeline for resolution. Additionally, FDA is requiring a manual extraction study to demonstrate that the labeled volume can be consistently withdrawn from the vials despite an existing in-process control to demonstrate fill volume within specifications

Satisfactory resolution of these issues is required for approval of the DefenCath NDA by a pre-approval inspection and/or adequate manufacturing facility responses addressing these concerns. If an inspection is required, the FDA is currently facing a backlog due to the pandemic and are actively working to define an approach for scheduling outstanding inspections once safe travel may resume [...].

52. On this news, the Company's stock price fell \$5.98 per share, or 39.87%, to close at \$9.02 per share on March 1, 2021. Despite this decline in the Company's stock price, the Company's securities continued to trade at artificially inflated prices because the Company

continued misrepresentations and omissions regarding the true scope of the deficiencies with respect to DefenCath's manufacturing process and/or at the facility responsible for manufacturing DefenCath.

53. For instance, on March 30, 2021, the Company issued a press release reporting the Company's results for the fourth fiscal quarter and full year of 2020 and providing a business update. That press release continued to generally advise that the "FDA noted concerns at the third-party manufacturing facility after a review of records requested by FDA and provided by the manufacturing facility and has requested a manual extraction study to demonstrate that the labeled volume can be consistently withdrawn from vials."

54. That same day, the Company hosted a conference call with investors and analysts to discuss, among other things, the regulatory pathway for the DefenCath NDA for CRBSIs. On that call, Defendant Mounts stated:

The timeline we outlined on March 1 and reiterated on March 9 for a planned meeting with the FDA in mid-April remains on track based on the progress we have made. We have been working intensely with our third-party manufacturing facility to develop the proposed resolutions to the deficiencies.

There has been a strong collaborative effort to develop responses for each of the six deficiencies identified by FDA for the manufacturing facility. In addition, we have developed the protocol for the manual extraction study being required by FDA to demonstrate that the labeled volume of the drug product can be consistently withdrawn from vials.

I am pleased to announce that FDA has granted our request to meet with them to begin resolving the outstanding deficiencies. As we have previously stated, the purpose of the meeting with FDA is to obtain agreement with the agency on the adequacy of our proposed plans for resolution of the deficiencies. Our contract manufacturing organization will join us in the meeting with FDA.

As we planned, the meeting will occur in mid-April, and we will provide an update on our progress and timeline for resolution of the deficiencies after the meeting with FDA. Our goal is to ensure that FDA can conclude that the manufacturing facility is ready to support commercial operation for DEFENCATH without the need for an onsite inspection.

As I have explained on previous calls, FDA identified the deficiencies based on a review of records that it had requested from the [contract manufacturing organization (“CMO”)].

55. On the same call, regarding the Company’s anticipated meeting with the FDA to discuss the DefenCath NDA, a JMP Securities analyst asked whether “you will actually have any of the work requested by FDA completed by the meeting, either in terms of documentation protocols, or the vial fill volume study or airflow visualization studies that they asked for,” and whether “you’ve actually completed any, or have any new data to take to the meeting?” In response, Defendant Mounts assured the market, “yes, we obviously were involved in developing the proposed responses”; that “[s]ome of those proposed responses involve existing documentation”; that “we make sure that we -- where we could, we provided information that was responsive to the deficiency”; and that “there is new information there for them to review for some of the responses.”

56. The JMP Securities analyst followed up by noting “[y]ou mentioned that there was a couple of questions related to equipment that was not relevant to DEFENCATH” and asked “[i]s it still your view that those parts of the CRL are for equipment not relevant to DEFENCATH?” In response, Defendant Mounts stated:

“Maybe, yes. Yes, Jason, the issue was planned expansion at the manufacturing facility, which involved installation of new equipment. That is new equipment not intended for manufacturer of DEFENCATH. So, the information that has been used and is in place is the appropriate equipment for DEFENCATH manufacture.”

57. On the same call, a Truist Securities analyst observed: “[T]he impression is that it was the [CMO’s] deficiencies, so what are you -- why do you need to be involved in addressing their issues? What is it that you can contribute to the CMO’s deficiencies?” In response, Defendant Mounts stated:

I think folks don't understand that there's a parallel process here. As you noted, we have direct control over documentation and information on manufacturing, that's submitted directly to the new drug application. As part of that process, FDA inspects the manufacturing facility and reviews documentation and the facility for its ability to manufacture that product in a commercial setting.

So the inspection by FDA, whether it's by records assessment or an onsite inspection, involves reviewing manufacturing records for the product in the NDA, but it also goes broader than that. It goes to the actual facility and the equipment to the maintenance and the training and the personnel.

So, it's a parallel process, but obviously they are intertwined and can't be separated, because FDA is there to look at the potential for that facility to manufacture the product that's the subject of the NDA.

58. Also, on March 30, 2021, the Company filed an annual report on Form 10-K with the SEC, reporting its financial and operating results for the quarter and year ended December 31, 2020 (the "2020 10-K"). The 2020 10-K advised:

As we announced in March 2021, the FDA has informed us that it will not approve the NDA for DefenCath in its present form. The FDA noted concerns at the third-party manufacturing facility after a review of records requested by the FDA and provided by the manufacturing facility. We are working with the manufacturing facility to develop plans for resolution of the deficiencies. Additionally, the FDA is requiring a manual extraction study to demonstrate that the labeled volume can be consistently withdrawn from the vials despite an existing in-process control to demonstrate fill volume within specifications. We expect to be able to complete this requirement expeditiously.

Satisfactory resolution of these issues is required for approval of the DefenCath NDA by a pre-approval inspection and/or adequate manufacturing facility responses addressing these concerns.

59. With respect to the Company's CMOs, the 2020 10-K assured investors that the Company is "confident that [its] CMO's [for DefenCath] have adequate capacity to produce the volumes needed, [and] that there exists a sufficient number of potential alternate sources for the drug substances required to produce our products, as well as third-party manufacturers[.]"

60. Appended as exhibits to the 2020 10-K were substantively the same SOX certifications as referenced in ¶ 38, signed by Defendants Baluch and David.

61. The statements referenced in ¶¶ 51-60 were materially false and misleading because the Company made false and/or misleading statements, as well as failed to disclose material adverse facts about its business, operations, and compliance policies. Specifically, the Company made false and/or misleading statements and/or failed to disclose that: (i) it had downplayed the true scope of the deficiencies regarding DefenCath's manufacturing process and/or at the facility responsible for manufacturing DefenCath; and (ii) as a result, its public statements were materially false and misleading at all relevant times.

62. On April 14, 2021, the Company issued a press release reporting "that it has met with the [FDA] to discuss proposed resolutions for the deficiencies identified in the [CRL] to CorMedix and the Post-Application Action Letter received by the third-party manufacturer (CMO) from FDA for the [NDA] for DefenCath" (the "April 2021 Press Release"). Specifically, that press release disclosed that the Company would have to take additional steps to meet the FDA's requirements for DefenCath's manufacturing process, stating:

Addressing FDA's concerns regarding the qualification of the filling operation may necessitate adjustments in the process and generation of additional data on operating parameters for manufacture of DefenCath. CorMedix and the CMO are currently evaluating available data to determine if additional process qualification will be needed with subsequent validation to address these issues.

The FDA stated that the review timeline would be determined when the NDA resubmission is received and that it expected all corrections to facility deficiencies to be complete at the time of resubmission so that all corrective actions may be verified during an on-site evaluation in the next review cycle, if the FDA determines it will do an onsite evaluation.

63. On this news, the Company's stock price dropped \$1.44 per share, or 15.37%, to close at \$7.93 per share on April 14, 2021. Despite this decline in the Company's stock price, the Company's securities continued to trade at artificially inflated prices because of the Company's continued misrepresentations and omissions regarding the true scope of the deficiencies with

respect to DefenCath's manufacturing process and/or at the facility responsible for manufacturing DefenCath.

64. For example, the April 2021 Press Release assured investors that “[r]epresentatives from both CorMedix and the CMO participated in the meeting with FDA to ensure that there is alignment on addressing the [FDA]’s concerns[.]” that “[t]here is now an agreed upon protocol for the manual extraction study identified in the CRL that FDA is requiring as confirmation of in-process controls to demonstrate that the labeled volume can be consistently withdrawn from the vials[.]” that “CorMedix expects to be able to complete this requirement in the next several weeks[.]” and that “CorMedix will provide updates on the timeline as resolution of the deficiencies proceeds.”

65. The statements referenced in ¶ 64 were materially false and misleading because they failed to disclose that the Company had downplayed the true scope of the deficiencies regarding DefenCath's manufacturing process and/or at the facility responsible for manufacturing DefenCath.

THE TRUTH FULLY EMERGES

66. On May 13, 2021, the Company issued a press release reporting its results for the first fiscal quarter of 2021 and providing a business update. That press release disclosed that “[b]ased on our analyses, we have concluded that additional process qualification will be needed with subsequent validation to address the deficiencies identified by FDA.”

67. That same day, the Company hosted a conference call with investors and analysts to discuss, the regulatory pathway for the DefenCath NDA for CRBSIs. On that call, Defendant Mounts stated:

As we have explained previously, the major focus of FDA's concerns was on the qualification of the filling operation and CorMedix and the CMO have been

evaluating available data to assess the need for adjustments in the manufacturing process and generation of additional data on operating parameters for manufacture of DEFENCATH.

Based on our analysis, we have concluded that additional process qualification will be needed with subsequent validation to address the deficiencies identified by FDA. As a result, our current plan is to be able to resubmit the defend cap NDA in the fourth quarter of 2021.

68. Dissatisfied with the Company's continued ambiguous and general descriptions of the deficiencies identified with DefenCath's manufacturing process and/or at the facility responsible for manufacturing DefenCath, a Needham & Company analyst pressed the Company for clearer details on the deficiencies and the Company's steps to address them, stating:

I and probably most other people on this call and investors [are not] necessarily regulatory experts for which I apologize for any deficiency in my own notes and trying to interpret things, ***but I can't imagine I'm alone in not being able to follow some of the details you guys have given.*** So I'm just hoping maybe with a little bit of extra breadth and maybe walk me through it, I ignored on these things, although I got to I have sapped through a bunch of these.

When you say you have additional qualification processes that need to address the FDA, and you think you can submit in the fourth quarter an NDA. And then later on, you were talking about some manufacturing, validation that you need beforehand as much as you can. And I get it. These are not easy questions, and there is a lot of uncertainties to deal with the FDA. But can you maybe timeline me through or just slowly, treat me like I'm not all that smart What the steps are that you think you need to achieve by this 4Q NDA submission? [Emphasis added].

69. Specifically pressed for more details and a clearer picture of the regulatory hurdles facing the Company's manufacturing for DefenCath, Defendant Mounts finally disclosed:

[I]t is a complicated process and that it is not simple, and like all technical work, needs to be conducted with precision and is subject to issues when something can go wrong. It is highly sophisticated equipment. And so there are times when there may be unexpected results obtained. FDA's concern as they express to us during our meetings with them focused on the filling operation, which is the process by which DEFENCATH is during a sterile procedure loaded into the vials and then the vials are kept.

They expect us to generate sufficient data to demonstrate that, that process is a

controlled process and is consistent with the agency's requirements for good manufacturing practice. So clearly, sterility is a very important part of that process, but also the accuracy in making sure the right volume of DEFENCATH is loaded into the vials. And we are talking about thousands of vials during the manufacturing run.

So as I said, it is a complicated process and technically very involved and involves a generation of a lot of data to make sure that the process itself is using the jargon qualified, which means all the equipment has been qualified for the intended use and every step in the manufacturing process has been qualified.

And that everything works as it is intended to produce the product that has to meet its specifications. So they are very detailed requirements on a chemical basis as well on a performance basis that is required for the product.

And so that process needs to be very robust, needs to be reproducible. And the burden is on the manufacturer to demonstrate that the facility can do that process reducibly and generate the required product for commercial distribution.

70. On this news, the Company's stock price fell \$1.51 per share, or 19.97%, to close at \$6.05 per share on May 14, 2021.

DERIVATIVE AND DEMAND FUTILITY ALLEGATIONS

71. Plaintiff brings this action derivatively in the right and for the benefit of the Company to redress injuries suffered and to be suffered as a direct and proximate result of the breaches of fiduciary duties by Defendants.

72. Plaintiff will adequately and fairly represent the interests of the Company and its shareholders in enforcing and prosecuting its rights and has retained counsel competent and experienced in derivative litigation.

73. Plaintiff is a current owner of CorMedix and has continuously been the owner of the CorMedix stock during all times relevant to the illegal and wrongful course of conduct alleged herein. Plaintiff understands her obligation to hold CorMedix stock throughout the duration of this action and is prepared to do so.

74. During wrongful course of conduct at the Company, the Board consisted of

Defendants Baluch, Dillione, Dunton, Kaplan, Lefkowitz, Costa and Duncan. Because of the facts set forth throughout this Complaint, demand on the Board to institute this action is not necessary because such a demand would have been a futile and useless act as discussed below.

75. Defendants face a substantial likelihood of liability in this action because they caused the Company to issue false and misleading statements concerning its future prospects. Because of his advisory, executive, managerial, and directorial positions with the Company, Defendants had knowledge of material non-public information regarding the Company and was directly involved in the operations of the Company at the highest levels.

76. Defendants either knew or should have known of the false and misleading statements that were issued on the Company's behalf and took no steps in a good faith effort to prevent or remedy that situation.

77. Defendants cannot exercise independent objective judgment about whether to bring this action or whether to vigorously prosecute this action. For the reasons that follow, and for reasons detailed elsewhere in this Complaint, Plaintiff has not made (and should be excused from making) a pre-filing demand on the Board to initiate this action because making a demand would be a futile and useless act.

78. Defendants approved and/or permitted the wrongs alleged herein to have occurred and participated in efforts to conceal or disguise those wrongs from the Company's unitholders or recklessly and/or with gross negligence disregarded the wrongs complained of herein and are therefore not disinterested parties.

79. Defendants authorized and/or permitted the false statements to be disseminated directly to the public and made available and distributed to unitholders, authorized and/or permitted the issuance of various false and misleading statements, and are principal beneficiaries

of the wrongdoing alleged herein, and thus, could not fairly and fully prosecute such a suit even if they instituted it.

80. Because of their participation in the gross dereliction of fiduciary duties, and breaches of the duties of due care, good faith, and loyalty, Defendants are unable to comply with their fiduciary duties and prosecute this action.

DEFENDANTS ARE NOT INDEPENDENT OR DISINTERESTED

Defendant Baluch

81. Defendant Baluch is the CEO of the Company, and therefore is not independent. As CEO, Defendant Baluch is an employee of the Company, and thus could not disinterestedly consider a demand for action that might require him to sue the directors that control his continued employment and/or fellow members of management with whom he works on a day-to-day basis.

82. As alleged herein, Defendant Baluch personally issued the misleading statements alleged herein and is named as a defendant in the securities class action entitled *Levon v. CorMedix, Inc. et al.*, Case 2:21-cv-16855 (D.N.J.) (the “Securities Class Action”). As a result, Defendant Baluch would be interested in a demand regarding his own wrongdoing and demand is futile as to him.

Defendants Lefkowitz, Dillione, Dunton

83. Defendants Lefkowitz, Dillione, Dunton served as members of the Audit Committee during the Relevant Period. Pursuant to the Audit Committee Charter, the Audit Committee Defendants were responsible for, *inter alia*, the effectiveness of the Company’s internal controls, the integrity of its financial statements, and aspects of risk management and legal and regulatory compliance that may affect the Company’s financial reporting. Defendants Lefkowitz, Dillione, Dunton failed to ensure the integrity of the Company’s internal controls, as

they are charged to do under the Audit Committee Charter and to issue false and misleading financial statements with the SEC. Thus, Defendants Lefkowitz, Dillione, Dunton breached their fiduciary duties, are not disinterested, and demand is excused as to them.

Defendants Baluch and Dunton

84. Defendant Baluch served as Senior Vice President and President Europe, Middle East & Africa of UCB, SA, or UCB, from January 2015 to April 2016, Senior Vice President and President of the European Region of UCB from February 2013 to December 2014, and Senior Vice President and Chief Marketing Officer of UCB from January 2010 to February 2013.

85. From 2007 to 2013, Defendant Dunton served as a senior executive at UCB, including as President of its North America business.

86. Defendants Baluch and Dunton have longstanding business and personal relationships with each other that preclude them from acting independently and in the best interests of the Company and the shareholders. Thus, demand upon Defendants Baluch and Dunton would be futile.

COUNT I

Against Defendants for Breach of Fiduciary Duties

87. Plaintiff incorporates by reference and re-alleges each and every allegation contained above, as though fully set forth herein.

88. Defendants owe the Company fiduciary obligations. By reason of their fiduciary relationships, Defendants owed and owe the Company the highest obligation of good faith, fair dealing, loyalty, and due care.

89. Defendants violated and breached their fiduciary duties of care, loyalty, reasonable inquiry, and good faith.

90. As a direct and proximate result of Defendants' failure to perform their fiduciary obligations, the Company has sustained significant damages. As a result of the misconduct alleged herein, Defendants are liable to the Company.

91. As a direct and proximate result of Defendants' breach of their fiduciary duties, the Company has suffered damage, not only monetarily, but also to its corporate image and goodwill. Such damage includes, among other things, costs associated with defending securities lawsuit, severe damage to the unit price of the Company, resulting in an increased cost of capital, the waste of corporate assets, and reputational harm.

COUNT II

Against Defendants for Abuse of Control

92. Plaintiff incorporates by reference and re-alleges each and every allegation set forth above, as though fully set forth herein.

93. Defendants' misconduct constituted an abuse of their ability to control and influence the Company.

94. As a direct and proximate result of Defendants' abuse of control, the Company sustained significant damages. As a result of the misconduct alleged herein, Defendants are liable to the Company.

COUNT III

Against Defendants for Waste of Corporate Assets

95. Plaintiff incorporates by reference and re-alleges each and every allegation set forth above, as though fully set forth herein.

96. As a result of the foregoing, and by failing to properly consider the interests of the Company and its public stockholders, Defendants have caused the Company to waste valuable

corporate assets, to incur many millions of dollars of legal liability and costs to defend unlawful actions, to engage in internal investigations, and to lose financing from investors and business from future customers who no longer trust the Company and its products.

97. As a result of the waste of corporate assets, Defendants are each liable to the Company.

98. Plaintiff, on behalf of CorMedix, has no adequate remedy at law.

COUNT IV

(Against Defendants Baluch, David and Mounts for Contribution for Violations of Sections 10(b) and 21D of the Exchange Act)

99. Plaintiff incorporates by reference and realleges each and every allegation contained above, as though fully set forth herein.

100. Defendants Baluch, David and Mounts are named as defendants in related securities class action. The conduct of these defendants, as described herein, has exposed the Company to significant liability under various federal and state securities laws by their disloyal acts.

101. The Company is named as a defendant in related Securities Class Action that alleges and asserts claims arising under § 10(b) of the Exchange Act. The Company is alleged to be liable to private persons, entities and/or classes by virtue of many of the same facts alleged herein. If the Company is found liable for violating the federal securities laws, the Company's liability will arise in whole or in part from the intentional, knowing, or reckless acts or omissions of all or some of the Defendants as alleged herein, who have caused the Company to suffer substantial harm through their disloyal acts. The Company is entitled to contribution and indemnification from these Defendants in connection with all claims that have been, are, or may be asserted against the Company by virtue of their wrongdoing.

102. As officers, directors and otherwise, Defendants Baluch, David and Mounts had the

power or ability to, and did, control or influence, either directly or indirectly, the Company's general affairs, including the content of its public statements, and had the power or ability to directly or indirectly control or influence the specific corporate statements and conduct that violated § 10(b) of the Exchange Act and SEC Rule 10b-5.

103. Defendants Baluch, David and Mounts are liable under § 21D of the Exchange Act, which governs the application of any private right of action for contribution asserted pursuant to the Exchange Act.

104. Defendants Baluch, David and Mounts have damaged the Company and are liable to the Company for contribution.

105. No adequate remedy at law exists for Plaintiff by and on behalf of the Company.

REQUEST FOR RELIEF

WHEREFORE, Plaintiff demands judgment as follows:

A. Determining that this action is a proper derivative action maintainable under law, and that demand is excused;

B. Awarding, against Defendants and in favor of the Company, the damages sustained by the Company as a result of Defendants' breaches of his fiduciary duties;

C. Directing the Company to take all necessary actions to reform and improve its corporate governance and internal procedures, to comply with the Company's existing governance obligations and all applicable laws and to protect the Company and its investors from a recurrence of the damaging events described herein;

D. Awarding Plaintiff judgment on each and every Count;

E. Awarding to Plaintiff the costs and disbursements of the action, including reasonable attorneys' fees, accountants' and experts' fees, costs, and expenses; and

F. Granting such other and further relief as the Court deems just and proper.

JURY DEMAND

Plaintiff demands a trial by jury on all issues so triable.

DATED: October 12, 2021

GAINEY McKENNA & EGLESTON

By: /s/ Barry J. Gainey

Barry J. Gainey
375 Abbott Road
Paramus, NJ 07652
Telephone: (201) 225-9001
Facsimile: (201) 225-9002
Email: bgainey@gme-law.com

GAINEY McKENNA & EGLESTON


Thomas J. McKenna
Gregory M. Egleston
501 Fifth Avenue, 19th Floor
New York, NY 10017
Telephone: (212) 983-1300
Facsimile: (212) 983-0383
Email: tjmckenna@gme-law.com
Email: egleston@gme-law.com

Attorneys for Plaintiff

VERIFICATION

I, MELISSA VOTER, am a plaintiff in the within action. I have reviewed the allegations made in this Shareholder Derivative Complaint, know the contents thereof, and authorize its filing. To those allegations of which I have personal knowledge, I believe those allegations to be true. As to those allegations of which I do not have personal knowledge, I rely upon my counsel and their investigation and believe them to be true.

I declare under penalty of perjury under the laws of the United States that the foregoing is true and correct. Executed this 4 day of October 2021



MELISSA VOTER